UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 24-CV-21625-BLOOM/Elfenbein

MARLEN ZAMORA,

Plaintiff,

v.

AAP IMPLANTS, INC.,

Defendant.
_____/

REPORT AND RECOMMENDATION

THIS CAUSE is before the Court upon Defendant AAP Implants, Incorporated's ("Defendant") Motion to Dismiss Counts I, III, VI, and VII of Plaintiff Marlen Zamora's ("Plaintiff") Second Amended Complaint with Prejudice (the "Motion"), ECF No. [46]. Plaintiff filed a Response in Opposition to the Motion (the "Response"), ECF No. [48], to which Defendant filed a Reply (the "Reply"), ECF No. [52]. The Honorable Beth Bloom referred the Motion to me for a Report and Recommendation. *See* ECF No. [51]. Having considered the Parties' filings and the relevant law, I recommend that the Motion be **DENIED** in part and **GRANTED** in part.

I. BACKGROUND

On February 15, 2024, Plaintiff commenced a products liability action against Defendant in the Eleventh Judicial Circuit in and for Miami-Dade County, Florida. *See* ECF No. [1-1] at 8-12. After being served with a copy of the Complaint, Defendant timely removed the state-court action to this Court based on the Parties' diversity of citizenship. *See* ECF No. [1] at ¶¶ 6-10. Once the case was removed, Defendant, on May 3, 2024, moved to dismiss Plaintiff's Complaint. *See generally* ECF No. [10]. Defendant's first motion to dismiss prompted Plaintiff to file an

amended complaint on June 4, 2024. *See generally* ECF No. [26]; ECF No. [22] (granting Plaintiff leave to file an amended complaint). Finding pleading deficiencies in the Amended Complaint, Defendant filed a second motion to dismiss on June 18, 2024, which prompted Plaintiff to file the Second Amended Complaint on July 16, 2024. *See generally* ECF No. [34]; ECF No. [46]; ECF No. [42] (granting Plaintiff leave to file the Second Amended Complaint). Still unsatisfied with Plaintiff's attempt to plead her claims, Defendant filed the instant Motion on August 1, 2024. *See generally* ECF No. [47].

The facts relevant to the resolution of the Motion are as follows: Defendant is an entity "engaged in the business of designing, developing, producing, manufacturing, distributing and selling medical devices used in surgical procedures[.]" ECF No. [46] at ¶ 6. Relevant to this action and the Motion before me, Defendant "designed, manufactured[,] and distributed" "LOQTEQ Straight Plate 3.5 [] and three different Cortical Screws 3.5[,]" (the "Device"). *Id.* at ¶ 5. On April 15, 2023, Plaintiff underwent surgery to treat her fractured arm. *See id.* at ¶ 9. During her surgery, Plaintiff's surgeons installed the Device in her arm to stabilize her fracture. *See id.* at ¶¶ 9-10. At an unspecified time following her surgery, the Device "br[oke], snapp[ed], split[], and/or crack[ed] inside" Plaintiff's arm while she was "performing a simple movement of lifting her hand to her mouth[.]" *Id.* at ¶ 16. Based on these allegations, Plaintiff filed the Second Amended Complaint raising the following seven claims: (1) Strict Liability/Defective Warning (Count I), *see id.* at ¶¶ 17-20; (2) Strict Liability/Design Defect (Count II), *see id.* at ¶¶ 21-24; (3) Strict Liability/Manufacturing Defect (Count III), *see id.* at ¶¶ 25-29; (4) Negligent Design (Count IV), *see id.* at ¶¶ 30-35; (5) Negligent Manufacturing (Count V), *see id.* at ¶¶ 36-47; (6) Negligent Failure to Warn (Count VI), *see id.* at ¶¶ 48-54; and (7) Negligent Failure to Test and Inspect (Count VII), *see id.* at ¶¶ 55-59.

In response to these allegations, Defendant asks the Court to dismiss Counts I, III, VI, and VII of Second Amended Complaint. *See generally* ECF No. [46]. First, Defendant argues that the Court should dismiss Counts I and VI because the learned intermediary doctrine bars them and the warning allegations are insufficient. *See id.* at 6-9. Next, Defendant asserts that the Court should dismiss Count III because Plaintiff failed to sufficiently allege the element of a manufacturing defect as opposed to a design defect. *See id.* at 9-11. Finally, Defendant contends that the Court should dismiss Count VII because negligent failure to test and inspect is not an independent cause of action under Florida law. *See id.* at 11-12. Defendant urges the Court to dismiss these counts with prejudice because this is Plaintiff's third attempt to properly plead these claims and further amendment would be futile. *See id.* at 12-13.

Plaintiff, for her part, opposes the Motion, arguing that (1) the learned intermediary doctrine does not bar Counts I and VI, *see* ECF No. [48] at 3-6, and (2) she has sufficiently pled the element of a manufacturing defect in Count III, *see id.* at 6-7. Plaintiff conspicuously fails to respond to Defendant's argument that negligent failure to test and inspect, which is the claim for relief in Count VII, is not an independent claim for relief under Florida law. *See generally id.* Finally, Plaintiff argues that, if the Court finds that Counts I, III, and VI are subject to dismissal, the Court should dismiss her claims without prejudice because she can cure the purported deficiencies Defendant identified. *See id.* at 7-8.

Defendant thereafter filed a timely Reply that largely reiterates the arguments from the Motion and highlights Plaintiff's failure to respond to its argument concerning Count VII, which operates as a concession. *See generally* ECF No. [52].

II. LEGAL STANDARDS

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Pleadings must contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citation omitted). Indeed, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Iqbal*, 556 U.S. at 679 (citing *Twombly*, 550 U.S. at 556).

To meet this "plausibility standard," a plaintiff must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Twombly*, 550 U.S. at 556). The standard "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* (quoting *Twombly*, 550 U.S. at 555). "[T]he standard 'simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence' of the required element." *Rivell v. Private Health Care Sys., Inc.*, 520 F.3d 1308, 1309-10 (11th Cir. 2008) (quoting *Twombly*, 550 U.S. at 545).

On a motion to dismiss, "the court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff." *Dusek v. JPMorgan Chase & Co.*, 832 F.3d 1243, 1246 (11th Cir. 2016) (citing *Erickson v. Pardus*, 551 U.S. 89, 94 (2007)). Unsupported factual allegations and legal conclusions, however, receive no such deference. *See Iqbal*, 556 U.S. at 679 ("While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations."). A complaint's "well-pled allegations must 'nudge the claims

across the line from conceivable to plausible.'" *Hays v. Page Perry, LLC*, 627 F. App'x 892, 896 (11th Cir. 2015) (alterations adopted; quoting *Twombly*, 550 U.S. at 555, 570).

III. DISCUSSION

For the reasons explained below, I recommend that (1) the Motion to Dismiss be granted with respect to Counts I, VI, and VII of the Second Amended Complaint and denied with respect to Count III of the Second Amended Complaint and (2) Plaintiff be granted *one final opportunity* to amend Counts I and VI of the Second Amended Complaint.

A. Motion to Dismiss

1. *Counts I and VI*

Defendant moves to dismiss Counts I and VI on the ground that the learned intermediary doctrine bars them. *See* ECF No. [47] 6-9. In support of this position, Defendant advances three arguments: First, Defendant explains that "[u]nder [the learned intermediary] doctrine, the manufacturer's duty to warn of a prescription product's risks runs to the physician, not the patient" and that Plaintiff failed "to set forth any allegations that a defective warning was provided" to her physician. *Id.* at 7-8 (citations omitted). Second, Defendant asserts that Plaintiff's allegations under Counts I and VI must fail because they focus on Defendant's failure to warn of the Device's alleged defects rather than the risks associated with its prescribed use. *See id.* at 8-9. Third, Defendant argues "that Plaintiff fails to reference anywhere in the Second Amended Complaint what the actual warnings accompanying the [Device] were or to explain how such warnings were inadequate or omitted risk information that would have resulted in a different prescribing decision by her doctor." *Id.*

In her Response, "Plaintiff maintains that the general allegations, incorporated into each cause of action, and the failure to warn counts, considered in tandem, clearly communicate that

among those whom Defendant failed to warn is [Plaintiff's] physician, or surgeon." ECF No. [48] at 5-6. However, Plaintiff fails to respond to Defendant's argument that her allegations improperly focused on the Device's alleged defects rather than its known risks or that she failed to plausibly allege each element of a failure-to-warn claim in Counts I and VI. *See generally id.*

"To succeed on a failure-to-warn claim [under Florida law], [a] 'plaintiff must show (1) that the product warning was inadequate; (2) that the inadequacy proximately caused her injury; and (3) that she in fact suffered an injury from using the product.'" *Salinero v. Johnson & Johnson*, 995 F.3d 959, 964 (11th Cir. 2021) (quoting *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1321 (11th Cir. 2017)). Furthermore, in pleading the elements of a failure-to-warn claim in the context of a medical device, a plaintiff must allege that the manufacturer failed to warn the patient's physician of the risks associated with a medical product's prescribed use, not its alleged defects. *See Dye v. Covidien LP*, 470 F. Supp. 3d 1329, 1340 (S.D. Fla. 2020) ("However, the inquiry is not whether the manufacturer warned of *defects*, the question is whether the manufacturer warned of *risks*." (citations omitted)). Finally, because Florida has adopted the learned intermediary doctrine, "the manufacturer's duty to warn runs to the physician, not to the patient[,]" *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007), meaning Plaintiff must "allege these factors with his [or her] physician in mind[,]" *Dimieri v. Medicis Pharms. Corp.*, No. 14-CV-176, 2014 WL 3417364, at *4 (M.D. Fla. July 14, 2014).

Upon review of the Second Amended Complaint, Plaintiff's allegations are too conclusory to plausibly allege failure to warn claims under Counts I and VI. First off, Defendant correctly asserts that nowhere in the Second Amended Complaint does Plaintiff allege that Defendant failed to warn her physician of the risks of using the Device. *See* ECF No. [46] at ¶¶ 5-20, 24, 30, 33, 48-54. Plaintiff maintains that this position is mistaken and points to a series of allegations in her

Second Amended Complaint that, when read together, plausibly allege that Defendant failed to warn her physician of the risks. *See* ECF No. [48] at 4-5. Specifically, Plaintiff directs the Court to (1) Paragraph 11 of her Second Amended Complaint in which she states that "[i]t was completely reasonable for Defendant to expect a surgeon to insert the DEVICE into Plaintiff's body during the April 15, 2023 surgery[,]" ECF No. [46] at ¶ 11; (2) the allegation in Count I where she states "[n]o warning was given whatsoever[,]" ECF No. [48] at 4 (quoting ECF No. [46] at ¶ 18); and (3) to the allegation in Count VI where she alleges Defendant had a duty to warn the "general public" and "users" of the Device's alleged defects, *id.* at 5 (quoting ECF No. [46] at ¶ 52). In making this strained argument, Plaintiff asks the Court to read language into the Second Amended Complaint that, simply put, does not satisfy the learned intermediary standard for a failure-to-warn claim. Instead, Plaintiff must clearly set forth the allegation that Defendant failed to warn her prescribing physician. *See Dye*, 470 F. Supp. 3d 1329, 1340 (S.D. Fla. 2020); *see also Dimieri*, No. 2:14-CV-176-FTM-38, 2014 WL 3417364, at *3 (M.D. Fla. July 14, 2014) ("While it is true Plaintiff alleged Defendant failed to warn Plaintiff and other people this statement is simply too vague to imply Plaintiff's physician had inadequate knowledge of the risks of Solodyn, even when favorably construed on behalf of Plaintiff." (quotation omitted; citing *Twombly*, 550 U.S. 544 and *Iqbal*, 556 U.S. 662)). Contrary to Plaintiff's argument, adding such an allegation would not be superfluous; it is necessary to allege a claim for relief.

Next, Counts I and VI are also subject to dismissal because Plaintiff, in the Second Amended Complaint, improperly focuses on the Device's alleged defects rather than the *risks* associated with its prescribed use. *See* ECF No. [46] at ¶¶ 5-20, 24, 30, 33, 48-54. At the outset of the Second Amended Complaint, Plaintiff characterizes the Device, generally, as being "unreasonably dangerous" and requiring independent inspection for defects by physicians before

its implementation during surgery. *See id.* at ¶¶ 12-13. And more specifically, Plaintiff alleges in Counts I and VI that the Device contained "structural defects[,]" "fabrication deficiencies[,]" "latent and pre-existing flaws[,]" and due to these defects, the Device was susceptible to "spontaneous[] break[age.]" *Id.* at ¶17; *see id.* at ¶ 49 ("At the time of sale, the DEVICE contained the Design Defects and DEVICE Manufacturing Defects that rendered it unsafe for the use of its intended purpose.").

Allegations that a prescription medical device is inherently defective are fundamentally different from allegations that an otherwise safe prescription medical device carries risks with its prescribed use. The former allegation would go to a claim for design defect, which requires a "plaintiff [to] prove[] that the design of [a] product proximately caused [] [his or her] injuries[,]" *Eghnayem.*, 873 F.3d at 1319 (11th Cir. 2017) (quoting *Force v. Ford Motor Co.*, 879 So. 2d 103, 106 (Fla. 5th DCA 2004)), while the latter would go to a failure-to-warn claim, *see Brito v. Cty. of Palm Beach*, 753 So. 2d 109, 112 (Fla. 4th DCA 1998) ("A warning should contain some wording directed to the significant dangers arising from failure to use the product in the prescribed manner, such as the risk of serious injury or death."). The distinction between these claim types exists because product defects require correction — not warning, whereas a non-defective prescription medical device should warn learned intermediaries of the possible risks associated with its proper use. *See Dye*, 470 F. Supp. 3d at 1340. In sum, in order for Counts I and VI to survive, Plaintiff must reframe her failure-to-warn claim around the Device's alleged *risks* and Defendant's failure to warn Plaintiff's *physician* of those alleged risks.

In addition to these two deficiencies, Defendant argues that Counts I and VI should be dismissed because Plaintiff fails to plausibly allege the first and second element of a failure-to-warn claim. To satisfy the first prong of the failure-to-warn test, Plaintiff alleges the Device's

warning was inadequate because of (1) its "wording[,]" (2) its "location" on the Device, and (3) "the manner in which the warning was conveyed[.]" ECF No. [46] at ¶ 18. In the alternative, Plaintiff alleges the Device's warning was inadequate because Defendant gave "[n]o warning . . . whatsoever[.]" *Id.* These allegations come close to plausibly alleging the first element of a failure-to-warn claim. *See Tsavaris v. Pfizer, Inc.*, No. 15-CV-21826, 2016 WL 375008, at *3 (S.D. Fla. Feb. 1, 2016) (finding that a plaintiff must "plead the content of the warning label *or otherwise describe the manner in which the warning was inadequate*" in order to plausibly allege a failure to warn claim (emphasis added; citing *Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 602 (11th Cir. 2008))). But, they nonetheless fail to satisfy the first element because Plaintiff fails to allege the risks associated with the Device's prescribed use. If the Device has no alleged risks associated with its use, there is no duty to provide a warning about the Device because — in that case — Plaintiff's physician would have had all the necessary information to "weigh[] the potential benefits against the dangers in deciding whether to recommend the [Device] to meet the [Plainitff's] needs." *Pierre v. Intuitive Surgical, Inc.*, 476 F. Supp. 3d 1260, 1278 (S.D. Fla. 2020), *aff'd*, 854 F. App'x 316 (11th Cir. 2021).

Even if Plaintiff properly pleaded the first element of a failure-to-warn claim, Counts I and VI would still be subject to dismissal because she failed to allege that the Device's inadequate warning was the proximate cause of her injuries. Interpreting Florida law, the Eleventh Circuit in *Eghnayem* held that "to satisfy the causation element, a plaintiff must show that her treating physician would not have used the product had adequate warnings been provided." 873 F.3d at 1321 (citing *Felix v. Hoffmann-LaRoche, Inc.*, 540 So.2d 102, 105 (Fla. 1989)). Having combed through the Second Amended Complaint, there are no allegations that explicitly claim that Plaintiff's physician would not have used the Device if it were not for Defendant's failure to warn.

See generally ECF No. [46]. Plaintiff must set forth such an allegation in an amended complaint if Counts I and VI are to survive. For the foregoing reasons, Plaintiff has failed to plausibly allege failure-to-warn claims and I, therefore, recommend that Counts I and VI be dismissed.

2. *Count III*

In the Motion to Dismiss, Defendant argues that Plaintiff's manufacturing defect claim — which she raises under Count III — must be dismissed because Plaintiff fails to allege that the Device "deviated from all other Products[] or failed to meet a manufacturing specification" and because Plaintiff's manufacturing defect claim is duplicative of her design defect claim. ECF No. [47] at 11. In the Response, Plaintiff argues that it is unnecessary at this stage of the pleadings to allege that the Device deviated from all other products manufactured by Defendant or that the Device failed to meet Defendant's manufacturing specifications. *See* ECF No. [48] at 6 (citing *Dye*, 470 F. Supp. 3d at 1336). Furthermore, Plaintiff implicitly argues that the substantial similarity between the allegations supporting her design and manufacturing defect claims is not fatal because pleading in the alternative is acceptable at the complaint stage of a case. *See id.* at 6-7 (citing *Dye*, 470 F. Supp. 3d at 1337). In the Reply, Defendant makes the *ipse dixit* assertion that "because Plaintiff affirmatively elected to assert the alleged underlying manufacturing defects with specificity, she then must distinguish those specific defects from her design defect allegations in order to adequately plead those claims." ECF No. [52] at 5 (citation omitted).

"To prove a manufacturing defect claim under Florida law, a plaintiff must prove that 1) the product was defective, 2) the defect existed at the time the product left the defendant-manufacturer's control, and 3) the defect proximately caused the plaintiff's injuries." *Salinero v. Johnson & Johnson*, 400 F. Supp. 3d 1334, 1343-44 (S.D. Fla. 2019) (citations omitted), *aff'd*, 995 F.3d 959 (11th Cir. 2021); *see also Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270,

1285 (M.D. Fla. 2009) ("Under Florida law, when the defect is a manufacturing defect, a product is defective if it is in a condition unreasonably dangerous to the user, and the product is expected to and does reach the user without substantial change affecting that condition." (quotation omitted)), *aff'd*, 634 F.3d 1296 (11th Cir. 2011). Manufacturing defects are "aberrational defects[,]" whereas design defects "occur[] throughout an entire line of products[.]" *Harduvel v. Gen. Dynamics Corp.*, 878 F.2d 1311, 1317 (11th Cir. 1989) (quotation omitted); *see also Benitez v. Synthes, Inc.*, 199 F. Supp. 2d 1339, 1344 (M.D. Fla. 2002) ("Manufacturing defects are generally limited to situations where something goes wrong in the manufacturing process and can be distinguished from other types of product liability claims such as design defects and inadequate warning defects." (citing *Cassisi v. Maytag Co.*, 396 So. 2d 1140, 1145 (Fla. 1st DCA 1981))).

Plaintiff's failure to allege a specific manufacturing defect is not a sufficient basis to dismiss Count III of the Second Amended Complaint. As the Eleventh Circuit explained in *Bailey*, "[i]t is difficult for a plaintiff at [the complaint] stage [of] litigation to know the source of the defect that was responsible for the harm caused: whether there was a surprising manufacturing problem, [or] a systemic issue with a product in its design[.]" 288 F. App'x at 605-06. Keeping with the Eleventh Circuit's holding in *Bailey*, Plaintiff should not be penalized for failing to possess and plead the specific facts involving the source of the defect that will likely come into her possession during the course of discovery. *See Krywokulski v. Ethicon, Inc.*, No. 09-CV-980, 2010 WL 326166, at *3 (M.D. Fla. Jan. 21, 2010) ("Florida law does not require that a plaintiff be required to plead design defect versus manufacturing defect during the complaint stage. Plaintiff's allegation of a defect alone is sufficient, as mere knowledge of a defect gives defendant enough notice to produce a proper response . . . ." (citing *Bailey*, 288 Fed. Appx. at 605)).

Similarly, Count III need not be dismissed because it is duplicative of Plaintiff's design

defect claim. As explained in *Dye*, the comingling of design and manufacturing defect claims is permitted at the complaint stage of litigation because "it is difficult for a plaintiff to determine, at this stage of the proceedings, whether the defect 'occurred in the assembly line as opposed to an overall design defect.'" 470 F. Supp. 3d at 1337 (quoting *Bailey*, 2006 WL 3665417 at *3). Plaintiff is entitled to the same leniency here.

Despite the holding in *Bailey* and the finding in *Dye*, Defendant urges the Court to disregard these cases and instead follow the finding in *Cates v. Zeltiq Aesthetics, Inc.*, No. 19-CV-1670, 2020 WL 13786612 (M.D. Fla. Mar. 11, 2020). *See* ECF No. [52] at 6. *Cates*, however, is distinguishable. The Court in *Cates* dismissed the manufacturing defect claim because the complaint only alleged that the medical device "was manufactured defectively" without any further explanation, so the complaint only contained "a legal conclusion devoid of factual support." *Id.* at *3. Having reviewed the factual allegations supporting Count III, the same cannot be said for Plaintiff's allegations as Plaintiff alleges the Device was "defectively manufactured *in such a manner that it was susceptible to crack propagation and would spontaneously break, split and/or crack following surgery*." *See* ECF No. [46] at ¶ 25 (emphasis added). Unlike in *Cates*, in which the Complaint simply alleged the device was defectively manufactured without more, here Count III specifically addresses the defect – the spontaneous breaking, splitting, or cracking following surgery. While Count III may not address the *source* of the defect, *Bailey*, *Dye*, and *Krywokulski,* all persuasively and instructively explain that such specific information is not necessary at the pleading stage. For the foregoing reasons, I recommend that Defendant's Motion to Dismiss as to Count III be denied.

3. *Count VII*

Finally, regarding Count VII, Defendant argues that "Florida law does not recognize an

independent cause of action for negligent failure to test" because "a claim for negligent testing is 'subsumed by [Plaintiff's] claims for defective design and failure to warn.'" ECF No. [47] at 11 (alteration in original; citation omitted; quoting *Small v. Amgen, Inc.*, 2 F. Supp. 3d 1292, 1299 (M.D. Fla. Mar. 6, 2014)). Plaintiff failed to respond to this claim and, therefore, conceded it. *See generally* ECF No. [48]; *see Jones v. Bank of Am., N.A.*, 564 F. App'x 432, 434 (11th Cir. 2014) ("[W]hen a party fails to respond to an argument or otherwise address a claim, the Court deems such argument or claim abandoned." (quotation omitted)). Because Plaintiff abandoned this claim, I recommend that Count VII of the Second Amended Complaint be dismissed.

B. Leave to Amend

The Second Amended Complaint is Plaintiff's third attempt to adequately plead her claims in this products liability action. *See supra* Background at 1-2. Defendant asserts that giving Plaintiff a fourth opportunity to amend her claims would be futile as Plaintiff has had the benefit of two motions to dismiss, "which clearly presented a roadmap for Plaintiff to cure the deficiencies" identified in the instant Motion. ECF No. [47] at 12-13 (citation omitted). Based on this procedural history, Defendant contends that the Court can reasonably conclude "that Plaintiff will never be able to fully and meaningfully plead Counts I, III, VI, and VII and therefore [should] dismiss these counts with prejudice[.]" *Id.* at 13.

With respect to Counts I and VI, there is no indication that amendment of these claims would be futile. Defendant cites to three cases in support of its position that Plaintiff should not be granted further leave to amend. *See* ECF No. [47] at 12-13; ECF No. [52] at 6-7. The first two cases Defendant cited contain significant factual distinctions that render their holdings inapplicable to this case. *See Reese v. Herbert*, 527 F.3d 1253, 1263 (11th Cir. 2008) ("The motion for leave to amend . . . *was filed nearly seven weeks after the close of discovery*. Because the period for

discovery had expired, granting the motion would have caused the defendants undue prejudice, as they would not have been able to conduct further discovery with respect to the claim the proposed amendment asserted." (emphasis added)); *Burger King Corp. v. Weaver*, 169 F.3d 1310, 1319-20 (11th Cir. 1999) (affirming the district court's decision to deny a plaintiff's motion for leave to amend because granting the motion, which was filed *40 months* after the original counterclaim was filed, would have created undue delay and would have required discovery of new facts and further amendment would have been futile).

And as for the third case, *Reiner v. Federal Express Corp.*, the district court denied leave to amend because the plaintiff had the benefit of the defendant's motion to dismiss, which explained the deficiencies in the complaint and, despite this, the plaintiff still failed to correct the deficiencies. *See generally* Case No., 22-CV-23001, 2023 U.S. Dist. LEXIS 71931 (S.D. Fla. Apr. 25, 2023). Here, Defendant raises the learned intermediary doctrine and its specific failure-to-warn arguments for the first time in the current Motion. *Compare* ECF No. [46] *with* ECF No. [10] and [34]. Thus, unlike *Renier*, Plaintiff did not have the benefit of knowing about those specific deficiencies in Counts I and VI at the time of filing the Second Amended Complaint. Therefore, it cannot be said that amendment would be futile under the circumstances.

Rather than dismissal with prejudice, I recommend that the district court exercise its broad discretion to grant Plaintiff leave to amend Counts I and VI because the identified pleading deficiencies can be easily cured through amendment and Plaintiff is likely to remedy those deficiencies in an amended pleading. *See In Re 3M Combat Arms Earplug Prod. Liab. Litig.*, No. 19-MD-2885, 2021 WL 8533256, at *3 (N.D. Fla. Oct. 8, 2021) ("[A]fter the time for amending a pleading as a matter of course has run, courts retain broad discretion to grant leave to amend and 'should freely give leave when justice so requires.'" (quoting Fed. R. Civ. P. 15(a)(2); citation

omitted)). In addition, looking at the current Order Setting Trial and Pre-trial Schedule, six months remain in the discovery period, giving the Parties ample time to engage in discovery involving the allegations in an amended pleading and thereby eliminating any potential prejudice to Defendant. With that said, the undersigned recognizes that this will be Plaintiff's fourth attempt to plead the claims for relief in this action, and for that reason, the undersigned recommends that Plaintiff be given *one final* opportunity to amend the claims by way of a Third Amended Complaint.

With regard to Count VII, however, Plaintiff abandoned that claim when she failed to respond to Defendant's argument for its dismissal. *See generally* ECF No. [48]. Important to the undersigned's decision here is the fact that the claim brought under Count VII does not exist independently in Florida's jurisprudence. *See Small*, 2 F. Supp. 3d at 1299. Because a claim for negligent failure to test does not exist and no amount of amendment would independently bring such a claim into existence under Florida law, amendment would indeed be futile and this claim should be dismissed with prejudice.[1] *See Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001) ("A district court need not, however, allow an amendment . . . where amendment would be futile." (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962))).

IV. CONCLUSION

For the foregoing reasons, I respectfully **RECOMMEND** that:

1. Defendant's Motion to Dismiss Counts I, III, VI, and VII of Plaintiff's Second Amended Complaint with Prejudice, **ECF No. [47]**, be **GRANTED** in part and **DENIED** in part;

[1] Because Count III is sufficient as pled, it is unnecessary to address whether Plaintiff should be granted leave to amend this claim.

2. Counts I and VI of the Second Amended Complaint be **DISMISSED WITHOUT PREJUDICE**. Should the Honorable Beth Bloom adopt this Report and Recommendation, Plaintiff should file a Third Amended Complaint **within 14 days** of the Report's adoption that cures the deficiencies in Counts I and VI of the Second Amended Complaint;
3. Defendant's Motion to Dismiss Count III of Plaintiff's Second Amended Complaint be **DENIED**;
4. Count VII of Plaintiff's Second Amended Complaint be **DISMISSED WITH PREJUDICE**.

Pursuant to Local Magistrate Rule 4(b), the parties have fourteen (14) days from the date of being served with a copy of this Report and Recommendation within which to file written objections, if any, with the Honorable Beth Bloom, United States District Judge. Failure to timely file objections shall bar the parties from a de novo determination by the District Judge of an issue covered in the Report and shall bar the parties from attacking on appeal unobjected-to factual and legal conclusions contained in this Report except upon grounds of plain error if necessary in the interest of justice. *See* 28 U.S.C. § 636(b)(1); *Thomas v. Arn*, 474 U.S. 140, 149 (1985); *Henley v. Johnson*, 885 F.2d 790, 794 (11th Cir. 1989); 11th Cir. R. 3-1.

DONE and ORDERED in Chambers in Miami, Florida on November 20, 2024.

MARTY FULGUEIRA ELFENBEIN
UNITED STATES MAGISTRATE JUDGE

cc: All Counsel of Record